CHLOROZOTOCIN

NSC - 178248

Chemical Name:2-[[[(2-Chloroethyl)nitrosoamino]carbonyl]-amino]-2-deoxy-<u>D</u>-glucopyranose

Other Name: DCNU

CAS Registry Number: 54749-90-5

Molecular Formula: $C_9H_{16}ClN_3O_7$ M.W.: 313.7

How Supplied: For injection, 50 mg, vial: supplied as a lyophilized powder with citric acid, 48 mg and sodium hydroxide to adjust the pH, in 10 mL amber vials.

Solution Preparation: 50 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP, each milliliter contains 10 mg of chlorozotocin buffered to pH 3.8 to 4.2 with citric acid and sodium hydroxide.

Storage: Refrigerate the intact vials (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 4 years at room temperature (22-25 °C). Intact vials were not stable when stored at elevated temperature (50 °C) for one year. An expiration date of 24 months for intact vials stored under refrigeration (2-8 °C) is used.

Constitution as recommended results in a solution that is chemically stable for 3 hours at room temperature (22-25 °C) and 24 hours under refrigeration (2-8 °C).

Further dilution to 0.1 mg/mL with 5% Dextrose Injection, USP, or 5% Dextrose in 0.9% Sodium Chloride Injection, USP, does not markedly affect stability.

CAUTION: This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous